

Remarks

By the present amendment, claim 28 has been amended; and claims 29, 31, 32, 34, 37, 38, 40-43, 46, and 48-50 have been cancelled without prejudice. Claims 51-54 are newly added. Claims 27, 35, 38, 43, 44, 46, and 51-54 are pending.

Support for the amendments is apparent, and no new matter is added. Reconsideration of the rejections is respectfully requested.

Priority

Applicants note the Examiner's statement regarding priority document U.K. 0024998.6. Applicant is in the process of obtaining a copy of the priority document and will submit it in due course.

Specification Informalities

The Examiner has noted the recitation of XL Fit software program. Applicants respectfully submit that the XL Fit program is well known in the art and is widely available. Further, one of ordinary skill in the art would recognize that production of antisera is well known in that art and does not require that the XL Fit program be used.

Claim Objections

The Examiner has objected to claims 28, 39, and 47 for minor informalities. Applicant submits that claims 28, 39, and 47 have been amended to obviate the Examiner's objections.

Claim Rejections - 35 U.S.C. §112, First Paragraph

Claims 28, 33, 35, 39, 44, 45, and 47 stand rejected under 35 U.S.C. §112, first paragraph for allegedly failing to meet the written description requirement. This rejection will be addressed as it pertains to currently pending claims as amended.

The Examiner asserts that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner asserted that the specification does not teach fragments of SEQ ID NO:2 and the properties of such fragments. The Examiner further alleges that the specification fails to teach

the structure or relevant identifying characteristics of fragments of SEQ ID NO:2, sufficient to allow one of skill in the art to determine that the inventor had possession of the invention as claimed.

Applicant respectfully disagrees. Applicant submits that the Notice, entitled, "Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, ¶1. Written Description" Requirement at p. 1104, vol. 66, no. 4 (January 5, 2001) addresses the written description provision as follows (emphasis added):

An applicant shows possession of the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing characteristics sufficient to show that the applicant was in possession of the claimed invention.

Applicant notes that the specification discloses an immunogenic fragment of a BASB111 polypeptide, that is a contiguous portion of the BASB111 polypeptide which has the same or substantially the same immunogenic activity as the polypeptide comprising the amino acid sequence of SEQ ID NO:2. In addition, the specification further describes preferred fragments including an isolated polypeptide comprising amino acid sequence having at least 15 or 20 contiguous amino acids of SEQ ID NO:2. Applicant submits that these recitations of the immunogenic fragments, coupled with the disclosed amino acid sequence of SEQ ID NO:2 establish possession of the invention by showing that the invention was "ready for patenting" by the disclosure of structural chemical formulas that show the invention was complete. Accordingly, reconsideration of the Written Description Requirement rejection under 35 U.S.C. 112, ¶1 is respectfully requested.

Claim Rejections - 35 U.S.C. §112, First Paragraph - Enablement

Claims 28, 33, 35, 39, 44, 45, and 47 stand rejected under 35 U.S.C. §112, first paragraph based on an assertion that the specification, while being enabling for a polypeptide comprising the sequence of the amino acid SEQ ID NO: 2 and a fusion protein comprising the amino acid

Serial No.: 10/018,672
Docket No.: BM45395

sequence SEQ ID NO:2, does not reasonably provide enablement for an isolated polypeptide that comprises a fragment of at least 15 or 20 amino acids, fusion protein or vaccine composition comprising said fragments.

Applicant respectfully puts forth that each of the currently pending claims are fully enabled and described by the specification. The specification of the instant application provides a full disclosure of the amino acid sequence of SEQ ID NO: 2 and the nucleotide sequence SEQ ID NO: 1, which encodes the polypeptide of SEQ ID NO: 2. The specification also provide substantial guidance for producing polypeptide fragments and further disclosed recombinant techniques for producing polypeptides. It should also be noted that it was well within the abilities and skill of one of ordinary skill in the art to produce polypeptides of various sizes using recombinant techniques, especially when provided with both the polypeptide and nucleotide sequences of a given protein. Thus, the invention as claimed is fully enabled. The Examiner's concerns regarding "unlimited and unknown amino acids of SEQ ID NO: 2" are misplaced. The claims of the instant application clearly define the metes and bounds of the instant invention, that is the amino acid sequence SEQ ID NO:2; and immunogenic fragments of at least 15 contiguous amino acids of SEQ ID NO:2 wherein the immunogenic fragment induces an antibody or T-cell mediated immune response that recognizes the polypeptide SEQ ID NO:2. Thus, the claims do not encompass "unlimited and unknown amino acids of SEQ ID NO: 2". At minimum, the specification teaches the polypeptide of SEQ ID NO: 2 and fragments thereof that induce an immune response. That these fragment may or may not be distinguishable from each other, as seems to be a concern of the Examiner, is not of importance as each of these fragments are encompassed by the instant invention, as one of ordinary skill in the art would immediately recognize. As such, Applicant puts forth that the currently pending claims are properly enabled and described by the instant specification.

With regard to the unpredictability of protein chemistry, Applicants note that the art has recognized the difficulties associated with processing of protein fragments, and has devised methods for overcoming inefficient processing of protein fragments in studies of human T-cell responsiveness. These methods were available at the time of the filing of the instant application and were within the purview of those of skill in the art. For instance, in Reece et al., *J. of Immunol.* 1993, 6175-6184 (which was attached as Exhibit A in Applicant's amendment of 4/19/04) the difficulties associated with inefficient protein processing in connection with studies

Serial No.: 10/018,672
Docket No.: BM45395

of T-cell responsiveness were recognized (p. 6175, ¶ 1). In Reece et al., the difficulties of protein processing were overcome by synthesizing overlapping dodecapeptides on pins to map T-cell epitopes of tetanus toxin. Pools of 20 peptides each were used to simplify the mapping assays. Thus, it was practical to synthesize a large number of peptides, and the initial screen needed only to assay sixty to seventy pools. Pools that generated strong responses were deconvoluted by assaying the members of the pool. That such experimentation using a multipin method to screen for antigens is ordinary in this art is illustrated in *Current Protocols in Immunology* 1997 9.7.1-9.7.19 (which was attached as Exhibit B to the amendment of 4/19/04) and Reece et al., 172 *J. of Immunol.* 1994 241 (previously attached as Exhibit C). The Examiner's concerns regarding "unlimited and unknown amino acids of SEQ ID NO: 2" are misplaced. The claims of the instant application clearly define the metes and bounds of the instant invention, that is the amino acid sequence SEQ ID NO:2; and immunogenic fragments of at least 15 contiguous amino acids of SEQ ID NO:2 wherein the immunogenic fragment induces an antibody or T-cell mediated immune response that recognizes the polypeptide SEQ ID NO:2. Thus, the claims do not encompass "unlimited and unknown amino acids of SEQ ID NO: 2". Consequently, given the teachings of the specification that includes the structural formula of SEQ ID NO:2 and experimental methods well-known in the art at the time of filing, Applicants assert that the claimed polypeptides are enabled.

In light of the above discussion, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

Claims 28, and 44-45 stand rejected under 35 U.S.C. §112, first paragraph based on an assertion that the specification does not provide the proper guidance for one of skill in the art to make and/or use the claimed invention.

Applicant respectfully disagrees. Claims 28 and 44-45 are directed to vaccines comprising the polypeptide of 28. The instant specification provides the proper guidance that one of skill in the art would need in order to make the claimed invention. In particular, on pages 37-42, the specification provides ample teachings that one of skill in the art would understand as fully enabling said claims. Furthermore, one of skill in the art would recognize that the experimentation required to make the invention of claims 44-45 is well within the normal experimentation in this art of making vaccines. This is fully supported by the McMichael

reference cited by the Examiner. This reference clearly shows that one of skill in the art would test potential vaccines in animal model, in effect this reference defines the exact type of experimentation that one would necessarily perform. Thus, this type of experimentation cannot be considered "undue". Thus, Applicant respectfully requests withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 U.S.C. §112, Second Paragraph

Claims 45 stands rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Office Action posits that claim 45 is vague, and that the metes and bounds of "one other antigen" in claim 44 is difficult to understand.

Without conceding the correctness of the rejection, Applicants have amended claim 45 to more particularly and distinctly claim the subject matter of the invention. Reconsideration of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Claim Rejections - 35 U.S.C. §102(b), Christensen et al.

Claims 28, 30, 33, 35, 44, and 45 stand rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Christensen et al. In particular, the Office Action asserts that Christensen et al. discloses outer membrane protein from whole cell lysate preparations from *N. meningitidis*. The Office Action notes that monoclonal antibodies were produced by immunizing mice with the OM preparation. The Office Action asserts that the disclosed composition, i.e., whole cell lysates from *Moraxella catarrhalis* inherently comprise the amino acid sequence as set forth in SEQ ID NO:2.

Applicant respectfully disagrees. A claim is anticipated only if each and every element is found, either expressly or inherently described, in the reference. See MPEP 2131. Moreover, the identical invention must be shown in as complete detail as is contained in the claim. Applicant submits that Christensen et al. does not identically disclose isolated polypeptide as claimed, especially in light of the fact that there is no disclosure regarding amino acid sequences in the Christensen et al. reference.. Christensen et al. does not anticipate or even suggest the invention as presently claimed. Accordingly, reconsideration of the rejection is respectfully requested.

Claim Rejections - 35 U.S.C. §102(b), Murphy et al.

Claims 28, 33, and 35 stand rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Murphy et al. The Office Action posits that the amino acid sequence taught by Breton anticipates the claimed invention.

Without conceding the correctness of the rejection, Applicants have amended claims 28, 33, and 35 to more particularly point out the sequences of the invention. The claimed isolate is not disclosed or suggested by Murphy et al. Accordingly, reconsideration of the rejection is respectfully requested.

Claim Rejections - 35 U.S.C. §102(e), Breton

Claims 28, 33, 35, 39, 44, 45, and 47 stand rejected under 35 U.S.C. §102(e) for allegedly being anticipated by Breton. The Office Action posits that the amino acid sequence taught by Breton anticipates the claimed invention.

Without conceding the correctness of the rejection, Applicants have amended claims 28, 33, 35, 39, 44, 45, and 47 to more particularly point out the sequences of the invention. The claimed isolate is not disclosed or suggested by Breton. Accordingly, reconsideration of the rejection is respectfully requested.

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DECHERT LLP

NO. 8473 P. 14

Serial No.: 10/018,672
Docket No.: BM45395

Conclusion

Applicant believes this response to be a full and complete response to all outstanding rejections in this application. As the application is believed to be in condition for allowance, Applicants respectfully request a Notice of Allowability. The Examiner is invited to contact the undersigned representative should any further issues arise

Respectfully submitted,

DECHERT LLP

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John W. Ryan

John W. Ryan
Reg. No. 33,771

Thomas M. Haas
Reg. No. 50,210

Dechert LLP
1775 I Street, N.W.
Washington, D.C. 20006
Telephone (202) 261-3375
Fax (202) 261-3333